

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Art Unit: 1619
MOESTRUP, et al.) Examiner:
Serial No.: 09/977,577) Washington, D.C.
Filed: October 16, 2001) July 5, 2002
For: FUNCTION OF A HAPTOGLOBIN-) Docket No.: MOESTRUP=1A
RECEPTOR AND THE USES...)

TECH CENTER 1600/2800

JUL 8 0 2002

RECEIVED

#8

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents
Washington, D.C. 20231

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

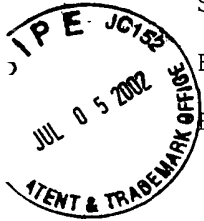
1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c).

[] i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign



USSN - 09/977,577

patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed (check no. _____).

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A check for the fee set forth in 1.17(i)(1), presently believed to be \$130 is enclosed (check no. _____). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-46, col. 2 (February 2000), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[X] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449

USSN - 09/977,577

be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

☐ A. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

☐ 3. Documents _____ are not in the English language. In accordance with 1.98(c), Applicants state:

- [] documents _____ already contain an English language abstract, summary or claim set.
- [] a publicly available abstract is attached to each of documents _____, and the source of each abstract is indicated thereon.
- [] documents _____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

- [] applicants have prepared an English translation of at least the pertinent portions of documents _____, and copies are attached.
- [] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [] A concise explanation of the relevance of documents _____ is set forth as follows:
[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

USSN - 09/977,577

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: _____

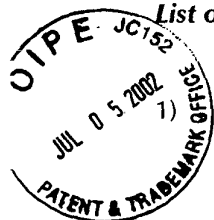
Iver P. Cooper
Reg. No. 28,005

624 Ninth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms
C:\MOESTRUP1A.PTO IDS.WPD

US patent application No. 09/977,577
 ProteoPharma ApS
 CD163
 Docket No.: MOESTRUP = 1A

RECEIVED
 JUL 8 0 2002
 TECH CENTER 1600/2900

List of references mentioned in the specification



- 1) Andris-Widhopf, J., Rader, C., Steinberger, P., Fuller, R., and Barbas, C. F., III, "Methods for the generation of chicken monoclonal antibody fragments by phage display", J Immunol Methods 242(1-2), 159-181 (August 28, 2000)
- 2) Birn, H. et al., "Characterization of an epithelial ~460-kDa protein that facilitates endocytosis of intrinsic factor-vitamin B₁₂ and binds receptor-associated protein", J. Biol. Chem. 272, 26497-26504 (October 1997)
- 3) Chander, R. et al., "Artificial viral envelopes containing recombinant human immunodeficiency virus (HIV) gp160", Life Sci. 50, 481-489 (1992)
- 4) Dubensky et al., "Direct transfection of viral and plasmid DNA into the liver or spleen of mice", Proc. Natl. Acad. Sci. USA 81, 7529-7533 (December 1984)
- 5) Epstein, A. L. et al., "Biology of the human malignant lymphomas. IV. Functional characterization of ten diffuse histiocytic lymphoma cell lines", Cancer 42, 2379-2391 (November 1978)
- 6) Ferry et al., "Retroviral-mediated gene transfer into hepatocytes *in vivo*", Proc. Natl. Acad. Sci. USA 88, 8377-8381 (October 1991)
- 7) Ghmati et al., "Identification of haptoglobin as an alternative ligand for CD11b/CD18, J. Immunol. 156, 2542-2552 (April 1, 1996)
- 8) Hatzoglu et al., "Hepatic gene transfer in animals using retroviruses containing the promoter from the gene for phosphoenolpyruvate carboxykinase", J. Biol. Chem. 265, 17285-17293 (October 5, 1990)
- 9) Hiebert et al., "E1A-dependent trans-activation of the human MYC promoter is mediated by the E2F factor", Proc. Natl. Acad. Sci. USA 86, 3594-3598 (May 1989)
- 10) Horn, I. R., Moestrup, S. K., van den Berg, B. M., Pannekoek, H., Nielsen, M. S., and van Zonneveld, A. J., "Analysis of the binding of pro-urokinase and urokinase-plasminogen activator inhibitor-1 complex to the low density lipoprotein receptor-related protein using a Fab fragment selected from a phage-displayed Fab Library", J. Biol. Chem. 270(20), 11770-11775 (May 1995)
- 11) Kaneda et al., "Increased expression of DNA cointroduced with nuclear protein in adult rat liver", Science 243, 375-378 (January 20, 1989)

US patent application No. 09/977,577
 ProteoPharma ApS
 CD163
 Docket No.: MOESTRUP = 1A

- 12) Kang, A. S., Burton, D. R., and Lerner, R. A., "Combinatorial immunoglobulin libraries in phage λ ", *Methods: A Companion to Methods in Enzymology* 2(2), 111-118 (April 1991)
- 13) Kozyraki, R., Fyfe, J., Kristiansen, M., Gerdes, C., Jacobsen, C., Cui, S., Christensen, E. I., Aminoff, M., de la Chapelle, A., Krahe, R., Verroust, P. J., and Moestrup, S. K., "The intrinsic factor-vitamin B₁₂ receptor, cubilin, is a high-affinity apolipoprotein A-I receptor facilitating endocytosis of high-density lipoprotein", *Nat. Med.* 5(6), 656-61 (June 1999)
- 14) Kristiansen, M., Kozyraki, R., Jacobsen, C., Nexø, E., Verroust, P.J., and Moestrup, S.K., "Molecular dissection of the intrinsic factor-vitamin B₁₂ receptor, cubilin, discloses regions important for membrane association and ligand binding", *J. Biol. Chem.* 274, 20540-20544 (July 16, 1999)
- 15) Kristiansen, M., Graversen, J.H., Jacobsen, C., Sonne, O., Hoffman, H., Alex Law, S.K., and Moestrup, S.K., "Identification of the hemoglobin scavenger receptor", *Nature* 409, 198-201 (January 2001)
- 16) Alex Law, S. K. et al., "A new macrophage differentiation antigen which is a member of the scavenger receptor superfamily", *Eur. J. Immunol.* **23**, 2320-2325 (September 1993)
- 17) Marks, J. D., Hoogenboom, H. R., Bonnert, T. P., McCafferty, J., Griffiths, A. D., and Winter, G., "By-passing immunization. Human antibodies from V-gene libraries displayed on phage", *J. Mol. Biol.* 222(3), 581-597 (September 1991)
- 18) Moestrup, S. K., Christensen, E. I., Sottrup-Jensen, L. & Gliemann, J., "Binding and receptor-mediated endocytosis of pregnancy zone protein-proteinase complex in rat macrophages", *Biochim. Biophys. Acta* 930, 297-303 (October 1, 1987)
- 19) Moestrup, S. K., Kaltoft, K., Sottrup-Jensen, L. & Gliemann, J., "The human α_2 -macroglobulin receptor contains high affinity calcium binding sites important for receptor conformation and ligand recognition", *J. Biol. Chem.* 265, 12623-12628 (July 1990)
- 20) Moestrup, S. K. & Gliemann, J., "Analysis of ligand recognition by the purified α_2 -macroglobulin receptor (low density lipoprotein receptor-related protein)", *J. Biol. Chem.* 266, 14011-14017 (July 1991)
- 21) Moestrup, S. K. et al., " β_2 -glycoprotein-I (apolipoprotein H) and β_2 -glycoprotein-I-phospholipid complex harbor a recognition site for the endocytic receptor megalin", *J. Clin. Invest.* 102, 902-909 (September 1998)

US patent application No. 09/977,577
 ProteoPharma ApS
 CD163
 Docket No.: MOESTRUP = 1A

- 22) Morishita R. et al., "Novel in vitro gene transfer method for study of local modulators in vascular smooth muscle cells", *Hypertension* 21, 894-899 (June 1993)
- 23) Nabel, E. G. et al., "Recombinant gene expression *in vivo* within endothelial cells of the arterial wall", *Science* 244, 1342-1344 (June 1989)
- 24) Pulford, K., Micklem, K., Alex Law, S. K. & Mason, D. Y., "CD163 (M130 antigen) workshop panel report", in *Leukocyte Typing VI*. (eds. Kishimoto, T. et al.) 1089-1091 (Garland Publishing Inc., New York, 1997)
- 25) Ritter et al., "The scavenger receptor CD163: regulation, promoter structure and genomic organization", *Pathobiology* 67, 257-261 (1999)
- 26) Schreier, H. et al., "Targeting of liposomes to cells expressing CD4 using glycosylphosphatidylinositol-anchored gp120", *J. Biol. Chem.* 269, 9090-9098 (March 1994)
- 27) Schreier, H., "The new frontier: gene and oligonucleotide therapy", *Pharm. Acta Helv.* 68, 145-159 (January 1994)
- 28) Schreier H. et al., "(Patho)physiologic pathways to drug targeting: artificial viral envelopes", *J. Mol. Recognit.* 8, 59-62 (January-April 1995)
- 29) Sizemore, D. R. et al., "Attenuated *Shigella* as a DNA delivery vehicle for DNA-mediated immunization", *Science* 270, 299-302 (October 1995)
- 30) Stecenko, A. A. et al., "Fusion of artificial viral envelopes containing respiratory syncytial virus (RSV) attachment (G) and fusion (F) glycoproteins with Hep-2-cells", *Pharm. Pharmacol. Lett.* 1, 127-129 (1992)
- 31) Van den Heuvel, M.M. et al., "Regulation of CD163 on human macrophages: cross-linking of CD163 induces signaling and activation", *J. Leukoc. Biol.* 66, 858-866 (November 1999)
- 32) Wejman, J. C., Hovsepian, D., Wall, J. S., Hainfeld, J. F. & Greer, J., "Structure and assembly of haptoglobin polymers by electron microscopy", *J. Mol. Biol.* 174, 343-368 (April 5, 1984)
- 33) U.S. Pat. No. 4,769,330 (Paoletti et al., 6 September 1988)
- 34) U.S. Pat. No. 5,155,020 (Paoletti, 13 October 1992)
- 35) U.S. Pat. No. 5,204,243 (Paoletti, 20 April 1993)
- 36) U.S. Pat. No. 5,225,336 (Paoletti, 6 July 1993)
- 37) U.S. Pat. No. 5,252,348 (Schreier et al., 12 October 1993)

US patent application No. 09/977,577
ProteoPharma ApS
CD163
Docket No.: MOESTRUP = 1A

Other relevant references

- 38) U.S. Pat. No. 5,928,913 (Efstathiou et al., 27 July 1999)
- 39) U.S. Pat. No. 5,962,667 (Jain et al., 5 October 1999)
- 40) U.S. Pat. No. 5,972,707 (Roy et al., 26 October 1999)
- 41) U.S. Pat. No. 5,972,899 (Zychlinsky et al., 26 October 1999)
- 42) U.S. Pat. No. 6,025,337 (Truong et al., 15 February 2000)
- 43) U.S. Pat. No. 6,046,314 (Gebe et al., 4 April 2000)
- 44) U.S. Pat. No. 6,063,901 (Tryggvason et al., 16 May 2000)